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EXAMINER	
STEADMAN, DAVID J	

ART UNIT	PAPER NUMBER
1656	

DATE MAILED: 07/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/076,416	RIEPING ET AL.	
	Examiner	Art Unit	
	David J. Steadman	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 January 2006 and 03 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-28 and 30-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-28,30-34 and 39-43* is/are rejected.

7)☒ Claim(s) *35-38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of the Application

[1] Claims 23-28 and 30-43 are pending in the application.

[2] Applicant's amendments to the claims, filed on 1/19/2006 and 5/3/2006, are acknowledged. The claim listing filed on 1/19/2006 fails to satisfy the requirements of 37 CFR 1.121 for the reason(s) set forth in the Office communication mailed on 4/4/2006. The claim listing filed on 5/3/2006 replaces all prior versions and listings of the claims.

[3] Receipt of a supplemental application data sheet, filed on 1/19/2006, is acknowledged.

[4] Applicant's arguments filed on 1/19/2006 and 5/3/2006 are acknowledged. The arguments filed on 5/3/2006 appear to be identical to those filed on 1/19/2006. Applicant's arguments have been fully considered and are deemed to be persuasive to overcome some of the rejections and/or objections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

[5] The text of those sections of Title 35 U.S. Code not included in the instant action can be found in a prior Office action.

Claim Objection

[6] Claim 24 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. The limitations of claim 24

have been incorporated into independent claim 23 and thus, claim 24 does not further limit claim 23.

[7] Claim 42 is objected to as being grammatically incorrect in the recitation of "prior to be inactivated" and "be" should be replaced with "being."

Claim Rejections - 35 USC § 112, Second Paragraph

[8] Claim(s) 34 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 34 is indefinite in the recitation of "AAC77180" and "AAC77179." In view of the specification (p. 10, top), it appears these are GenBank Accession Numbers. First, it is noted that, according to the claim, these Accession Numbers refer to genes, *i.e.,* nucleic acids, however, the sequences disclosed by the Accession Numbers appear to be polypeptide sequences (Appendix A). Second, it is unclear as to the information that is intended as being referenced by these Accession Numbers as the information of an Accession Number is frequently updated and modified. According to MPEP 2173.05(b), "[a] claim may be rendered indefinite by reference to an object that is variable." Indeed, the sequence revision histories of AAC77180 and AAC77179 (Appendix B) indicate that the information disclosed in these Accession Numbers has been updated numerous times. It is suggested that applicant clarify the meaning of AAC77180 and AAC77179.

Claim Rejections - 35 USC § 112, First Paragraph

[9] Claims 23-28 and 30-43 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

MPEP § 2163 states, "when filing an amendment an applicant should show support in the original disclosure for new or amended claims" and "[i]f the originally filed disclosure does not provide support for each claim limitation, or if an element which applicant describes as essential or critical is not claimed, a new or amended claim must be rejected under 35 U.S.C. 112, para. 1, as lacking adequate written description."

Claim 23 (claims 24-28 and 30-43 dependent therefrom) has been amended to include the limitation of "concentrating the L-amino acid in the medium and/or the Escherichia cells." In the instant response, applicant points to p. 3 of the specification as showing support for this limitation. However, while the specification at p. 3, bottom would appear to support the limitation of concentrating the L-amino acid in the medium or the cells, it does not support the "and/or" recitation.

Also, claims 30-31 have been amended to recite a source, *i.e.*, E. coli or C. glutamicum, for each of genes. In the instant response, applicant points to pp. 9-10 of the specification as showing support for these limitations. However, while the disclosure at pp. 9-10 of the specification supports a specific species of each genus of genes, this disclosure fails to support the genus of any E. coli or C. glutamicum gene as encompassed by the claims.

Thus, the added limitations to claims 23 and 30-31 are considered to be new matter. Applicant is invited to show support for the limitations at issue.

It should be noted that a similar rejection of claim 30 was raised in a prior Office action (Office action mailed on 9/27/2004 at p. 9, ¶ 27) and in response to this rejection, claim 30 was amended to remove the recitation of "*Escherichia coli*" or "*Coryneform glutamicum.*"

[10] The written description rejection of claims 23-28, 30-34, and 39-41 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the rejection is overcome by amendment to limit the microorganism to the genus *Escherichia* and the specification describes the *Escherichia* poxB gene and the encoded protein.

Applicant's argument is not found persuasive. The disclosure of a single representative species of modified microorganisms, *i.e., Escherichia coli* comprising an inactivated poxB gene, wherein the poxB gene has the nucleotide sequence of SEQ ID NO:1, and the inactivated poxB gene encodes a non-functional poxB polypeptide, is acknowledged. However, this single representative species fails to reflect the wide variation among the members of the genus and thus the single representative species fails to adequately describe all members of modified *Escherichia* microorganisms as encompassed by the claims. First, it is noted that the genus is not limited to *Escherichia coli,* but encompasses any *Escherichia* bacterium. Even assuming *arguendo* the genus

of microorganisms was limited to *Escherichia coli,* it is noted that numerous species of *Escherichia coli* are known as evidenced by the specification at p. 5, top and there is no evidence of record that the poxB gene from *E. coli* strain K12 is representative of poxB genes from all other *Escherichia* or *Escherichia coli* microorganisms. Even assuming *arguendo E. coli* strain K12 poxB gene disclosed as SEQ ID NO:1 is representative of all other *Escherichia* or *Escherichia coli* poxB genes, it is noted that there is no indication that the poxB gene to be inactivated be limited to the endogenous or naturally-occurring poxB gene. For example, the existing *Escherichia* – prior to modification – can have an altered poxB gene. As noted in the prior Office action, the functional definition of the genus does not provide any structural information commonly possessed by members of the genus which distinguish the nucleic acid species within the genus from other nucleic acids such that one can visualize or recognize the identity of the members of the genus. Furthermore, it is noted that there is no requirement that the "inactivated poxB gene which encodes a pyruvate oxidase" encode a non-functional polypeptide. For example, deletion mutagenesis to delete 5'- and 3'- nucleotides from the poxB gene, which is encompassed by the claim, would likely not result in the partially deleted poxB gene encoding a non-functional polypeptide. As such, both the "structure" and the "function" of the modified microorganism of the genus *Escherichia* are widely variant. While MPEP § 2163 acknowledges that in certain situations "one species adequately supports a genus", it is also acknowledges that "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus."

Also, it is noted that the prior Office action addressed the lack of adequate written description of the genus of genes as recited in claims 30-31 and modified microorganisms overexpressing or having inactivations thereof, which applicant does not dispute. The court generally accepts as fact that which is not disputed by applicant. See *In re Kunzmann*, 140 USPQ 235 (CCPA 1964).

Given the lack of description of a representative number of genes, the specification fails to sufficiently describe the claimed invention in such full, clear, concise, and exact terms that a skilled artisan would recognize that applicant was in possession of the claimed invention.

[11] The scope of enablement rejection of claims 23-28, 30-34, and 39-41 under 35 U.S.C. 112, first paragraph, is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in a prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the rejection is overcome by amendment to limit the microorganism to the genus *Escherichia* and the specification describes the *Escherichia* poxB gene and the encoded protein.

Applicant's argument is not found persuasive. The examiner maintains the position that the specification fails to enable the full scope of the claimed invention. Regarding claim 23, the claim broadly encompass the use of any *Escherichia* microorganism that has an "inactivated poxB gene which encodes a pyruvate oxidase," wherein inactivation is achieved by the methods recited in claim 23. As noted above, there is no requirement that the "inactivated poxB gene which encodes a pyruvate

oxidase" encode a non-functional polypeptide and the claim has been broadly interpreted as meaning that the *Escherichia* microorganism can have deletions of a poxB gene at the 5'- and/or 3'-ends, which are able to encode truncated albeit functional poxB polypeptide. The disclosure of a single working example of modified microorganisms, *i.e., Escherichia coli* comprising an inactivated poxB gene, wherein the poxB gene has the nucleotide sequence of SEQ ID NO:1, and the inactivated poxB gene encodes a non-functional poxB polypeptide, is acknowledged. However, even among species of *Escherichia coli,* a plurality of different strains exists (specification at p. 4, top) and there is no evidence of record of a structural relationship among poxB genes of all species of the genus of *Escherichia* bacteria so that one could use the disclosed methods for inactivating the poxB genes in all *Escherichia* bacteria as encompassed by the claims. While methods of isolating homologous genes in related organisms were known in the art at the time of the invention, it was not routine in the art to isolate all poxB genes in all microorganisms of the *Escherichia* genus and to modify the corresponding microorganism to inactivate its poxB gene.

Also, it is noted that the prior Office action addressed the lack of enabling disclosure for the full scope of genes as recited in claims 30-31 and modified microorganisms overexpressing or having inactivations thereof, which applicant does not dispute. The court generally accepts as fact that which is not disputed by applicant. See *In re Kunzmann*, 140 USPQ 235 (CCPA 1964).

Thus, in view of the overly broad scope of the claims, the lack of guidance and working examples provided in the specification, the high level of unpredictability, and

the amount of experimentation required, undue experimentation would be necessary for a skilled artisan to make and use the entire scope of the claimed invention. Applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims. The scope of the claims must bear a reasonable correlation with the scope of enablement (*In re Fisher*, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Claim Rejections - Double Patenting

[12] The provisional obviousness-type double patenting rejection is maintained for the reasons of record and the reasons stated below. The rejection was fully explained in the prior Office action.

RESPONSE TO ARGUMENT: Applicant argues the application in rejection part [c] is the same as the instant application and that the applications in rejection parts [o], [w], and [z] are abandoned. Applicant requests the rejection be held in abeyance with respect to the remaining applications.

Applicants' argument is not found persuasive. It is noted that the application in rejection part [c] is 10/483,416, while the instant application is 10/076,416. As such, the applications are not the same. Regarding the applications in rejection parts [w] and [z],

the examiner acknowledges these applications are abandoned. Regarding the application in rejection part [o], it is noted that the examiner inadvertently entered "10/619,309" instead of "10/616,309." It is the 10/616,309 application that is provisionally rejected herein for the reasons of record. As to the remaining applications, the rejection is maintained.

[13] The examiner reminds applicant that an earnest attempt has been made to identify those patents and/or co-pending applications for purposes of rejecting or provisionally rejecting the claims for double patenting. However, it is noted that numerous co-pending applications have been filed and/or continue to be filed, and/or patents have issued disclosing subject matter that is related to the instant application. In the interest of compact prosecution, the examiner requests that: 1) applicants identify any patent(s) and/or co-pending application(s) that claim(s) subject matter that may necessitate a double patenting rejection, an obviousness-type double patenting rejection, a provisional double patenting rejection, or a provisional obviousness-type double patenting rejection; 2) identify the claims of the patents and/or co-pending applications that claim identical or similar subject matter; 3) identify the corresponding claims of the instant application, and 4) take the appropriate action, *e.g.,* cancel claims to preempt a statutory double patenting rejection and/or file a terminal disclaimer to preempt an obvious-type double patenting rejection or provisional rejection. Applicants' cooperation in following steps 1) to 4) above is appreciated as this will allow the examiner to focus on more substantive issues in the examination of the instant application.

Claim Rejections - 35 USC § 102/103

[14] Claim(s) 23-28, 33, 40, and 42-43 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Chang et al. (*J Bacteriol* 154:756-762; cited in the Office action mailed on 10/19/2005). The claims are drawn to a method for producing an L-amino acid by fermenting an *Escherichia* bacterium with an inactivated poxB gene by culturing said bacterium, concentrating the L-amino acid in the medium and/or bacterium and isolating the L-amino acid.

Chang et al. teaches an *E. coli* mutant with an inactivated poxB gene, wherein the gene is inactivated by insertion of a transposon into the poxB gene (see, *e.g.,* p. 758, Table 2 and p. 759, right column). Chang et al. teaches culturing of the *E. coli* mutant and recovering a cell-free extract from the crude cellular lysate (see, *e.g.,* p. 756, right column). This anticipates claims 23-28, 33, 40, and 42-43 as written.

For purposes of clarifying the record, the following examiner's comments are provided. While Chang et al. does not teach isolation of *only* an L-amino acid from the cultured cells, Chang et al. does teach isolation of a cell-free extract from a crude cellular preparation, which would comprise L-amino acids, including L-threonine, L-valine, and L-lysine, which are endogenously produced by *E. coli.* In accordance with MPEP 2111, it is the examiner's position that isolation of the cell-free extract from the crude cellular preparation is considered to be "isolating the L-amino acid" from the cellular debris. In this case, there is no definition of the term "isolating" with respect to

an L-amino acid in the specification and there is no limitation in the claim that requires the L-amino acid to be free of additional elements of a cell-free extract. Applicant does not appear to dispute this interpretation.

While applicant argues Chang et al. does not teach concentrating the L-amino acid in the medium and/or the cells and that there is no teaching or suggestion in Chang et al. to lead an ordinarily skilled artisan to do such, it is the examiner's position that the culturing step of the method of Chang et al. inherently incorporates the recited concentration step. Initially, the culture medium of Chang et al. would have a relatively low concentration of bacterially-produced L-amino acids, however, by mere culturing of the bacterium of Chang et al., which would secrete L-amino acids into the medium, the concentration of bacterially-produced L-amino acids would necessarily increase over time. Also, if one takes into account normal evaporation of water in the culture medium, the concentration of the bacterially produced L-amino acid would also necessarily increase by merely culturing the cell of Chang et al.

[15] Claim(s) 23-28, 33 and 41-43 are rejected under 35 U.S.C. 102(b) as being anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Grabau et al. (*J Biol Chem* 264:12510-12519, 1989; cited in the IDS filed on 7/20/2004). The claims are drawn to a method for producing an L-amino acid by fermenting an *Escherichia* bacterium with an inactivated poxB gene by culturing said bacterium, concentrating the L-amino acid in the medium and/or bacterium and isolating the L-amino acid.

Grabau et al. teaches an *E. coli* transformed with a vector expressing a poxB gene deleted at the C-terminal end by insertion of a stop codon within the coding sequence, wherein the resulting encoded protein lacks detectable poxB activity (p. 12511, left column, middle and Figure 1). Grabau et al. teaches culturing of the *E. coli* expressing the deletion mutant and recovering a cell-free extract from the crude cellular lysate (see, *e.g.,* p. 12518, left column). This anticipates claims 23-28, 33, and 41-43 as written.

For purposes of clarifying the record, the following examiner's comments are provided. While Grabau et al. does not teach isolation of *only* an L-amino acid from the cultured cells, Grabau et al. does teach isolation of a crude extract from a cellular preparation, in which the crude extract would comprise L-amino acids, including L-threonine, L-valine, and L-lysine, which are endogenously produced by *E. coli.* In accordance with MPEP 2111, it is the examiner's position that isolation of the cell-free extract from the crude cellular preparation is considered to be "isolating the L-amino acid" from the cell culture and cellular debris. In this case, there is no definition of the term "isolating" with respect to an L-amino acid in the specification and there is no limitation in the claim that requires the L-amino acid to be free of additional elements of a cell-free extract. Applicant does not appear to dispute this interpretation.

Further, it is the examiner's position that the culturing step of the method of Grabau et al. inherently incorporates the recited concentration step. Initially, the culture medium of Grabau et al. would have a relatively low concentration of bacterially-produced L-amino acids, however, by mere culturing of the bacterium of Grabau et al.,

which would secrete L-amino acids into the medium, the concentration of bacterially-produced L-amino acids would necessarily increase over time. Also, if one takes into account normal evaporation of water in the culture medium, the concentration of the bacterially produced L-amino acid would also necessarily increase by merely culturing the cell of Grabau et al.

Claim Rejections - 35 USC § 103

[16] The rejection of claim(s) 23-28, 30-34, and 39-41 under 35 U.S.C. 103(a) as being unpatentable over Riepling et al. (US Patent 6,916,637) in view of Dusch et al. (US Patent Application Publication 2005/0196848), Chang et al. (*supra*), and Grabau et al. (*Nucleic Acids Res* 14:5449-5460; cited in the IDS filed on 9/3/2002) is withdrawn in view of applicant's statement that both Riepling et al., Dusch et al., and the instant application were commonly owned at the time the inventions were made. This statement satisfies the requirements for prior art disqualification under 35 U.S.C. 103(c). See particularly MPEP 706.02(l)(1).

[17] Claim(s) 39 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grabau et al. (*supra*) in view of Yoder et al. (*DNA Cell Biol* 19:401-408, 2000). Claim 39 limits the method of modifying the *Escherichia* bacterium to deletion mutagenesis.

Grabau et al. discloses the aforementioned teachings. Grabau et al. further teach that their future studies will include characterization of the isolated alpha- and beta-peptides of PoxB and additional C-terminal mutants (p. 12516, right column, bottom).

The deletion mutants of Grabau et al. were constructed by insertion of a stop codon into the poxB coding sequence, not by deletion mutagenesis to delete at least one base pair in the poxB gene.

Yoder teaches a method for creating nested deletions of a coding sequence by PCR amplification of a desired coding sequence fragment and insertion of that fragment into an expression vector (see particularly p. 402).

Therefore, it would have been obvious to one of ordinary skill in the art to combine the teachings of Grabau et al. and Yoder et al. for an *E. coli* transformed with an expression vector comprising coding sequence of the alpha- and beta-peptides of PoxB and additional C-terminal mutants created by the method of Yoder et al. One would have been motivated to create these deletion mutants by the method of Yoder et al. because, in the case of the alpha- and beta-peptides, this method provides for deletion of C-terminal sequence *as well as N-terminal sequence*, and for the additional C-terminal mutants, the PCR method of PCR deletion mutation of Yoder et al. is a functional equivalent of the method for deletion of Grabau et al. One would have a reasonable expectation of success for creating an *E. coli* transformed with an expression vector comprising coding sequence of the alpha- and beta-peptides of PoxB and additional C-terminal mutants by the method of Yoder et al. because of the results of Grabau et al., which discloses the nucleic acid sequence of poxB, and Yoder et al., which discloses the PCR method and cloning of the deletion fragments into an expression vector. Therefore, claim 39, drawn to the method described above would have been obvious to one of ordinary skill in the art at the time of the invention.

Conclusion

[18] Status of the claims:

Claims 23-28 and 30-43 are pending.

Claims 23-28, 30-34, and 39-43 are rejected.

Claims 35-38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

No claim is in condition for allowance.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Steadman whose telephone number is 571-272-0942. The examiner can normally be reached on Monday to Friday, 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr can be reached at 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David J. Steadman, Ph.D.
Primary Examiner
Art Unit 1656